

## **PSJ2 Exh 117**

## SETTLEMENT AND MEMORANDUM OF AGREEMENT

This Memorandum of Agreement (“Agreement”) is entered into by and between the United States Department of Justice (“DOJ”), the United States Drug Enforcement Administration (“DEA”), and Walgreen Co. and its wholly owned subsidiaries (“Walgreens”) (each a “Party” and collectively the “Parties”).

### APPLICABILITY

This Agreement shall be applicable to Walgreens Corporate and any facility owned or operated by Walgreens that is or was registered with DEA to dispense, distribute, or otherwise handle controlled substances or List I chemicals. Unless explicitly stated herein, nothing contained in this Agreement will lessen, supplant or expand Walgreens’ legal obligations under any statute, regulation, or law.

### PROCEDURAL BACKGROUND

1. Walgreens owns or operates (or has previously owned or operated) distribution centers that are or were registered with DEA as distributors of Schedule II-V controlled substances under provisions of the Controlled Substances Act, 21 U.S.C. §§ 801 et seq., (“CSA” or “the Act”) (each a “Distribution Center,” collectively the “Distribution Centers”).
2. Walgreens owns or operates (or has previously owned or operated) pharmacies that are or were registered with DEA as Retail/Chain Pharmacies to handle Schedule II-V controlled substances under the CSA (each a “Pharmacy,” collectively the “Pharmacies”). Walgreens owns or operates (or has previously owned or operated) Central Pharmacy Operations facilities that are or were registered with DEA as Retail/Chain Pharmacies or Central Fill Pharmacies to handle Schedule II-V controlled substances under the CSA (each a “CPO Facility,” collectively the “CPO Facilities”).
3. On April 7, 2011, Walgreens entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with DEA. See Appendix A.
4. Walgreens’ Jupiter Distribution Center (“Walgreens Jupiter”) is registered with DEA as a distributor of Schedule II-V controlled substances at 15998 Walgreens Drive, Jupiter, Florida 33478 (Registration RW0277752).
5. On September 13, 2012, the DEA, by its Administrator, Michele M. Leonhart, issued an Order to Show Cause and Immediate Suspension of Registration (“OTSC/ISO”) to Walgreens Jupiter. See Appendix B. After Walgreens requested an administrative hearing before DEA, the Administrative Law Judge (“ALJ”) docketed the case, *In the Matter of Walgreen Co.*, Docket No. 13-1.
6. On November 26, 2012, the DEA, by its Deputy Assistant Administrator, Joseph T. Rannazzisi, issued three OTSCs to Walgreens Retail Pharmacy (1) #03629, 12028 Majestic Boulevard, Hudson, Florida 34667 (Registration BW4713992); (2) #04727, 4950 South U.S. Highway 1, Fort Pierce, Florida 34952 (Registration BW6561270); and

- (3) #06997, 785 Lockwood Boulevard, Oviedo, Florida 32765 (Registration BW8487438). See Appendix C. After Walgreens requested an administrative hearing on each of these three matters, the ALJ docketed each case, *In the Matter of Walgreen Co.*, respectively Docket Nos. 13-9, 13-10, and 13-11.
7. On February 4, 2013, the DEA, by Deputy Assistant Administrator Rannazzisi, issued an OTSC to Walgreens Retail Pharmacy #03836, 9332 U.S. Highway 19, Port Richey, Florida 34668 (Registration AW8830247). See Appendix C. After Walgreens requested an administrative hearing, the ALJ docketed the case, *In the Matter of Walgreen Co.*, Docket No. 13-16.
8. On February 11, 2013, the DEA, by Deputy Assistant Administrator Rannazzisi, issued an OTSC to Walgreens #04391, 2501 Virginia Avenue, Fort Pierce, Florida 34981 (Registration BW5872494). See Appendix C. After Walgreens requested an administrative hearing, the ALJ docketed the case, *In the Matter of Walgreen Co.*, Docket No. 13-18.
9. Finally, on February 19, 2013, the DEA, by Deputy Assistant Administrator Rannazzisi, issued an OTSC to Walgreens #03099, 1525 Colonial Boulevard, Fort Myers, Florida 33907 (Registration AW1366877). See Appendix C. After Walgreens requested an administrative hearing, the ALJ docketed the case, *In the Matter of Walgreen Co.*, Docket No. 13-20.
10. On February 22, 2013, the ALJ consolidated the seven cases into one consolidated proceeding that was scheduled for an Administrative Hearing initially on January 7, 2013, and then continued until February 25, 2013, and again until April 23, 2013.

#### STIPULATION AND AGREEMENT

The facts alleged in the OTSC/ISO issued to Walgreens Jupiter, as well as the facts alleged in the government's filings in *In the Matter of Walgreen Co.*, Docket No. 13-1, as listed in Appendix B, would, if proven, constitute grounds under which DEA could revoke the DEA registration of Walgreens Jupiter. The facts alleged in the OTSCs issued to Walgreens #03629, #04727, #06997, #03836, #04391, and #03099, as well as the facts alleged in the government's filings in *In the Matter of Walgreen Co.*, Docket Nos. 13-9, 13-10, 13-11, 13-16, 13-18, and 13-20, as listed in Appendix C, would, if proven, constitute grounds under which DEA could revoke the DEA registrations of Walgreens #03629, #04727, #06997, #03836, #04391, and #03099.

Walgreens acknowledges that suspicious order reporting for distribution to certain pharmacies did not meet the standards identified by DEA in three letters from DEA's Deputy Assistant Administrator, Office of Diversion Control, sent to every registered manufacturer and distributor, including Walgreens, on September 27, 2006, February 7, 2007 and December 27, 2007. Furthermore, Walgreens acknowledges that certain Walgreens retail pharmacies did on some occasions dispense certain controlled substances in a manner not fully consistent with its compliance obligations under the CSA (21 U.S.C. §§ 801 et seq.) and its implementing regulations (21 C.F.R. Part 1300 et seq.). Finally, Walgreens acknowledges that its



recordkeeping practices regarding the dispensing of controlled substances from certain retail pharmacies utilizing its CPO Facilities as central-fill pharmacies did not require such original prescriptions to be marked "CENTRAL FILL."

Walgreens, DEA, and DOJ agree as follows:

I. General

1. Intention of Parties to Effect Settlement. In order to avoid the uncertainty and expense of litigation, and in furtherance of the Parties' belief that a settlement in these administrative matters is in the public interest, the Parties desire to settle and resolve, and hereby do settle and resolve, the administrative matters within DEA's enforcement authority and civil penalty matters arising under the CSA and its implementing regulations relating to (1) the conduct described in the OTSC/ISO issued to Walgreens Jupiter, and in DEA's filings in *In the Matter of Walgreen Co.*, Docket No. 13-1; (2) the conduct described in the OTSCs issued to Walgreens #03629, #04727, #06997, #03836, #04391, and #03099, and in DEA's filings in *In the Matter of Walgreen Co.*, Docket Nos. 13-9, 13-10, 13-11, 13-16, 13-18, and 13-20; (3) recordkeeping obligations of the CPO Facilities and Pharmacies; (4) other allegations regarding Covered Conduct identified in Section I.2 of this Agreement involving any other Walgreens DEA registrant; and (5) any other allegations relating to conduct arising under the CSA or its implementing regulations which DEA or DOJ knows or has reason to know of as of the effective date of this Agreement, regardless of whether DEA or DOJ has notified Walgreens of such allegations, including conduct at any Walgreens registrant where DEA or DOJ has an open investigation. This includes the open civil investigation into the above-referenced conduct in the United States Attorney's Office for the Southern District of Florida, as well as open civil investigations in the United States Attorney's Offices for the District of Colorado, the Eastern District of Michigan, and the Eastern District of New York. This also includes civil investigations by DEA Field Offices nationwide. The Parties further believe that the terms and conditions of this Agreement as set forth below represent a complete resolution of these matters.
2. Covered Conduct. For purposes of this Agreement, "Covered Conduct" shall mean the following, whether it occurred at a specific Walgreens DEA registrant or elsewhere within Walgreens:
  - a. Distribution Centers
    - (1) Conduct alleged in the September 13, 2012 OTSC/ISO issued to Walgreens Jupiter, and in DEA's filings in *In the Matter of Walgreen Co.*, Docket 13-1, as listed in Appendix B, and similar allegations regarding any other Walgreens Distribution Center, occurring on or before the effective date of this Agreement;
    - (2) Failure regarding any Distribution Center to maintain effective controls against the diversion of controlled substances into other than legitimate medical, scientific and industrial channels, as required by 21 U.S.C. §§



823(b) and (e), including any failures to conduct adequate due diligence to ensure that controlled substances were not diverted into other than legitimate channels, on or before the effective date of this Agreement;

- (3) Failure regarding any Distribution Center to timely detect and report suspicious orders of controlled substances as required by 21 U.S.C. § 823 and/or 21 C.F.R. § 1301.74(b) on or before the effective date of this Agreement;
- (4) Distributing controlled substances to pharmacies by any Distribution Center that the Distribution Center knew or should have known were engaged in any of the Covered Conduct listed in Section I.2.b of this Agreement on or before the effective date of this Agreement;
- (5) Failure regarding any Distribution Center to make complete and accurate ARCOS reports, on or before the effective date of this Agreement;
- (6) Refusal or negligent failure by any Distribution Center to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under the CSA and its implementing regulations, on or before the effective date of this Agreement; and
- (7) Conduct regarding any Distribution Center inconsistent with the CSA and its implementing regulations on or before the effective date of this Agreement.

b. Walgreens Pharmacies and CPO Facilities

- (1) Conduct alleged in the November 26, 2012, February 4, 2013, February 11, 2013, and February 19, 2013 OTSCs issued to Walgreens #03629, #04727, #06997, #03836, #04391, and #03099, and in DEA's filings in *In the Matter of Walgreen Co.*, Docket Nos. 13-9, 13-10, 13-11, 13-16, 13-18, and 13-20, as listed in Appendix C, and similar allegations regarding any other Walgreens Pharmacy or CPO Facility, occurring on or before the effective date of this Agreement;
- (2) Failure of Walgreens Pharmacists at any Pharmacy or CPO Facility to exercise their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R. § 1306.04(a), and dispensing by any Pharmacy, or CPO Facility, of controlled substances pursuant to purported prescriptions that were otherwise invalid under 21 C.F.R. Part 1306, on or before the effective date of this Agreement;

- (3) Dispensing by any Pharmacy or CPO Facility of controlled substances to individuals Walgreens knew or should have known were diverting controlled substances on or before the effective date of this Agreement;
  - (4) Dispensing by any Pharmacy or CPO Facility of controlled substances pursuant to prescriptions issued by a physician who did not have a current, valid DEA registration on or before the effective date of this Agreement;
  - (5) Refusal or negligent failure by any Pharmacy or CPO Facility to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under the CSA and its implementing regulations, including, but not limited to, failure by any Pharmacy or CPO Facility to maintain accurate records pursuant to 21 C.F.R. Part 1304 and to properly label and/or mark prescriptions pursuant to 21 C.F.R. Part 1306, on or before the effective date of this Agreement;
  - (6) Conduct inconsistent with the CSA and its implementing regulations on or before the effective date of this Agreement, by any Pharmacy or CPO Facility; and
  - (7) Failure by any Walgreens registrant, including any Pharmacy or CPO Facility, to adhere to the provisions of the April 7, 2011 Administrative Memorandum of Agreement between Walgreen Co. and DEA (the "2011 MOA").
3. Effect of 2011 MOA. The obligations contained in the 2011 MOA are superseded by the obligations contained within this Agreement.
  4. Term of Agreement. The obligations contained in this Agreement shall remain in full force and effect for a period of three (3) years from the effective date of this Agreement unless the Parties agree in writing to an earlier termination, provided, however, that the releases in Paragraphs II.6 and II.8 in this Agreement extend beyond the effective date.

## II. Terms and Conditions

1. Obligations of Walgreens Distribution Centers.
  - a. Walgreens will continue to review, and where reasonable and appropriate, to revise its processes and practices for conducting suspicious order monitoring and reporting suspicious orders from Walgreens' pharmacies, as set forth in the attached Addendum.
  - b. Walgreens shall inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b) in a format mutually and reasonably agreed upon by the Parties.
  - c. Walgreens agrees to the surrender of Walgreens Jupiter's DEA Registration RW0277752 for controlled substances Schedules II-V, until September 13, 2014.



2. Obligations of Walgreens Pharmacies and CPO Facilities.

- a. Walgreens agrees to maintain a compliance program in an effort to detect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations, as set forth in the attached Addendum. This program shall include procedures to identify the common signs associated with the diversion of controlled substances. The program shall also include the routine and periodic training of all Walgreens pharmacy employees responsible for dispensing controlled substances on the elements of the compliance program and their responsibilities under the CSA and applicable DEA regulations. This compliance program shall apply to all Walgreens Pharmacies and CPO Facilities.
- b. Walgreens shall implement and maintain policies and procedures in an effort to ensure that prescriptions for controlled substances are only dispensed to authorized ultimate users pursuant to federal and state law and regulations. Walgreens shall maintain its current policy that requires all customers to provide identifying information and shall also require valid photo identification as required by and in accordance with controlling state law where the pharmacy is located. Documents maintained by Walgreens pursuant to any obligation under federal and/or state law regarding the verification of an ultimate user's identity shall be kept readily available by the pharmacy, and shall be produced to DEA agents, task force officers or investigators on request.
- c. Walgreens shall direct and train its pharmacists that their corresponding responsibility under federal law requires them not to fill a prescription that such pharmacist knows or has reason to know was issued for other than a legitimate medical purpose or by a practitioner acting outside the usual course of professional practice.
- d. In connection with Walgreens' recordkeeping obligations, Walgreens agrees to maintain records regarding the dispensing of controlled substances in electronic format, in addition to the regularly maintained paper files, including records relating to which Distribution Center and/or CPO Facility shipped the controlled substance to the Pharmacy. These records shall be made available to DEA agents, task force officers or investigators, upon demand, without the need for a warrant or subpoena, provided that the DEA agents, task force officers or investigators present appropriate identification. Walgreens shall provide electronic reports of dispensing on an ad hoc basis in response to DEA requests within a reasonable time.
- e. Walgreens agrees to the surrender of the DEA registrations to dispense controlled substances for Schedules II-V at the following facilities until May 26, 2014: BW4713992 (#03629), BW6561270 (#04727), BW5872494 (#04391), AW8830247 (#03836), AW1366877 (#03099), and BW8487438 (#06997).



3. Walgreens General Obligations.

- a. Walgreens' policy and procedure is to cooperate with the government in any investigation. Walgreens agrees to reasonably cooperate with DEA, United States Attorneys' Offices, and any other law enforcement agency investigating or prosecuting customers of Walgreens' pharmacies for alleged violations or activities related to the Covered Conduct, unless such matters would affect the rights or obligations of Walgreens in regard to any pending or threatened litigation. Such cooperation shall include, but is not limited to, producing records and making employees available for interviews as reasonable and appropriate with reasonable notice in advance. However, nothing in this paragraph shall be construed as a waiver by Walgreens, its directors, officers or employees of any constitutional rights or rights that they would have as a party to a matter involving pending or threatened litigation with the government or a third party, including without limitation attorney-client or attorney work product privileges.
- b. Walgreens agrees that it will promptly move to dismiss, with prejudice, the pending lawsuit by Walgreens in Case No. 12-1397 in the United States Court of Appeals for the District of Columbia Circuit.
- c. Walgreens agrees to pay the United States eighty million dollars (\$80,000,000.00) ("the Settlement Amount") within ten (10) days of the effective date of this Agreement by electronic funds transfer pursuant to written instructions provided to Walgreens by the United States Attorney's Office for the Southern District of Florida.

4. Obligations of DEA.

- a. DEA agrees to accept at DEA Field Offices the information regarding suspicious orders as required under 21 C.F.R. § 1301.74(b) in the manner described in the attached Addendum.
- b. Within five (5) business days of the effective date of this Agreement, DEA agrees to unlock the controlled substances storage area at Walgreens Jupiter and make its contents available to Walgreens for any lawful transfer or reverse distribution of the inventory contained therein to an appropriate DEA registrant(s).
- c. Provided that Walgreens submits a re-application for each of the above-listed facilities at least four (4) months prior to the end of the applicable surrender period, DEA agrees that, upon application by Walgreens, it will grant (1) a DEA registration to distribute controlled substances in Schedules II-V for Walgreens Jupiter on or before September 13, 2014, and (2) DEA registrations to dispense controlled substances in Schedules II-V for the Walgreens Pharmacies listed in Paragraph II.2.e on or before May 26, 2014.

5. Joint Obligations of the Parties.

- a. Walgreens and DEA agree that upon the execution of this Agreement, DEA and Walgreens shall promptly file a joint motion with the ALJ to terminate all pending administrative proceedings against Walgreens.

6. Release by the United States. In consideration of the fulfillment of the obligations of Walgreens under this Agreement, the United States agrees to:

- a. Release Walgreens and all Walgreens facilities, including Walgreens subsidiary entities, affiliates, and registrants, along with their respective officers, directors, employees, successors, and assigns (collectively, the "Released Parties") from any administrative claims related to Covered Conduct prior to the effective date of this Agreement within DEA's enforcement authority under the CSA and its implementing regulations, and any corresponding DOJ authority for civil penalty claims under 21 U.S.C. § 842.
- b. Refrain from filing or taking any administrative actions against the Released Parties within DEA's enforcement authority under the CSA and its implementing regulations based on the Covered Conduct, or other noncompliant conduct to the extent that such conduct was or could have been discovered by DEA through the exercise of due diligence through the examination of investigations and inspections in existence as of the effective date of this Agreement, or the review of the reports and records Walgreens submitted to DEA prior to the effective date of this Agreement; and
- c. Refrain from filing any action for civil penalty claims under 21 U.S.C. § 842 by any U.S. Attorney's Office and/or DOJ based on the Covered Conduct, or other noncompliant conduct to the extent that such conduct was or could have been discovered by DEA through the exercise of due diligence through the examination of investigations and inspections in existence as of the effective date of this Agreement, or the review of the reports and records Walgreens submitted to DEA prior to the effective date of this Agreement.

7. Notwithstanding the releases by the United States in Paragraph #6 above, DEA reserves the right to seek to admit evidence of Covered Conduct for proper evidentiary purposes in any future administrative proceeding against Walgreens for non-Covered Conduct. Further, nothing in this Agreement shall prohibit or limit any other agency within DOJ, any State attorney general, or any other law enforcement, administrative, or regulatory agency of the United States or any State thereof, from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct. DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any agency that initiated an investigation, action, or proceeding involving Covered Conduct, but will not otherwise initiate or refer any civil action to any U.S. Attorney's Office or to any component of DOJ, based on the Covered Conduct. At Walgreens' request, DEA and DOJ agree to disclose the terms of this Agreement to any other agency and will represent, assuming



Walgreens is in compliance with this Agreement, that the allegations raised by DEA, as defined in the Covered Conduct, have been adequately addressed.

8. Release by Walgreens. Walgreens fully and finally releases the United States of America, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which Walgreens has asserted, could have asserted, or may assert in the future against the United States of America, its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.
9. Reservation of Claims. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including Walgreens) are the following:
  - a. Any potential criminal liability;
  - b. Any civil, criminal or administrative liability arising under Title 26, United States Code (Internal Revenue Code); or
  - c. Any liability based upon such obligations as are created by this Agreement.
  - d. Nothing in this Agreement constitutes an agreement by the United States concerning the characterization of the settlement amount for purposes of the Internal Revenue Laws, Title 26 of the United States Code.
10. Walgreens agrees that any and all costs it has or will incur in connection with this matter—including payment of the Settlement Amount under this Agreement, attorney's fees, costs of investigation, negotiation, and remedial action—shall be unallowable costs for government contracting accounting and for Medicare, Medicaid, TriCare, and FEHBP (or any other government reimbursement program) for reimbursement purposes.

### III. Miscellaneous

1. Binding on Successors. This Agreement is binding on Walgreens, and its respective successors, heirs, transferees, and assigns.
2. Costs. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.
3. No Additional Releases. This Agreement is intended to be for the benefit of the Parties and the Released Parties only, and by this instrument the Parties do not release any claims against any other person or entity other than the Parties.
4. Incorporation of Addendum. This Agreement incorporates a separate document, entitled "Addendum: Prospective Compliance," containing additional compliance measures to be undertaken by Walgreens.



5. Effect of Agreement. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement, and each of the Parties expressly agrees and acknowledges that, other than those statements expressly set forth in this Agreement, it is not relying on any statement, whether oral or written, of any person or entity with respect to its entry into this Agreement or to the consummation of the transactions contemplated by this Agreement. Any modifications to this Agreement shall be set forth in writing and signed by all Parties.

Walgreens represents that this Agreement is entered into with advice of counsel and knowledge of the events described herein. Walgreens further represents that this Agreement is voluntarily entered into in order to avoid litigation, without any degree of duress or compulsion.


6. Execution of Agreement. This Agreement shall become effective on the date of signing by the last signatory (the "Effective Date"). The United States agrees to notify Walgreens immediately when the final signatory has executed this Agreement.
7. Notices. All communications and notices to Walgreens pursuant to this Agreement shall be made in writing to the following individuals, which notice information may be altered from time to time by Walgreens providing written notification to DEA:
- a. Dwayne A. Piñon, Director, Pharmacy Law, Operations & Services, Walgreen Co., 104 Wilmot Road, MS #1434, Deerfield, Illinois 60015; fax: 847-315-4660; email: [dwayne.pinon@walgreens.com](mailto:dwayne.pinon@walgreens.com).
8. Disclosure. Walgreens and DEA may each disclose the existence of this Agreement and information about this Agreement to the public without restriction.
9. Execution in Counterparts. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement.
10. Authorizations. The individuals signing this Agreement on behalf of Walgreens represent and warrant that they are authorized by Walgreens to execute this Agreement. The individuals signing this Agreement on behalf of DEA and DOJ represent and warrant that they are signing this Agreement in their official capacities and that they are authorized by DEA and DOJ to execute this Agreement.
11. Choice of Law and Venue. This Settlement Agreement and Release shall be construed in accordance with the laws of the United States, and any Party may seek judicial enforcement of this Agreement upon a material breach by the other Party. The Parties agree that the jurisdiction and venue for any dispute arising between and among the Parties relating to this Agreement will be the United States District Court or, as appropriate, in the Court of Federal Claims, in which the Walgreens facilities and/or registrations at issue are located. This provision, however, shall not be construed as a waiver of the jurisdictional provisions of the CSA.

IN WITNESS WHEREOF, the Parties hereto have duly executed this Memorandum of Agreement.

**On Behalf of Walgreen Co.:**

  
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Thomas J. Sabatino  
Executive Vice President, General Counsel and Corporate Secretary  
Walgreen Co.

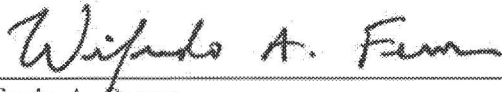
Dated: 6/10/13

  
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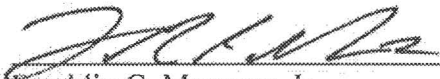
Dated: June 10, 2013

On Behalf of the United States Department of Justice:



Wifredo A. Ferrer  
United States Attorney  
Southern District of Florida

Dated: 6/11/13



Franklin G. Monsour, Jr.  
Assistant United States Attorney  
Southern District of Florida

Dated: 6/11/13



**On Behalf of the United States Drug Enforcement Administration:**



Michele M. Leonhart  
Administrator  
United States Drug Enforcement Administration

Dated: 6/10/13

### **Addendum: Prospective Compliance**

The Parties agree that Walgreens will maintain the following specific compliance measures for the duration of this Agreement. To the extent any compliance measures identified below are not yet in place, Walgreens commits to implement such measures within the timeframes specified herein.

#### **A. General**

1. Walgreens will maintain a Department of Pharmaceutical Integrity, composed of personnel with pharmacy-related training and managerial personnel, who shall be trained in relevant diversion-related issues, to coordinate compliance efforts related to controlled substances. Within one (1) month of the effective date of this Agreement, Walgreens will identify a dedicated contact point (including a dedicated email address) for DEA within the Department of Pharmaceutical Integrity to facilitate Walgreens' responses to DEA requests for information and documents, specifically including responses to requests for dispensing log data and pseudoephedrine data.

#### **B. Pharmacies**

1. Upon request by DEA to Walgreens' Department of Pharmaceutical Integrity, within two (2) business days Walgreens will provide to DEA, via appropriate secure means of electronic transmission, controlled substance dispensing logs consisting of those categories of information the regulations require dispensers to maintain as records, *see* 21 C.F.R. § 1304.22(c). DEA understands and agrees that additional reasonable time may be required to the extent DEA seeks additional data or information not regularly maintained for such logs.
2. For all Schedule II controlled substance prescriptions, Walgreens currently affixes a sticker to each paper prescription containing certain dispensing information such as: a serial number unique to each prescription (which includes a suffix identifying the dispensing retail pharmacy); the prescriber's name, address, telephone number, and DEA registration number; the patient's name, address, and telephone number; the prescription issue date; the drug and quantity dispensed; and the fill date. Walgreens currently also affixes such stickers to Schedule III-V controlled substance paper prescriptions in certain states, but not others, depending upon state law requirements. Within three (3) months of the effective date of this Agreement, Walgreens pharmacies will affix such a sticker to all paper controlled substance prescriptions in each state, regardless of the requirements of state law. Walgreens will maintain a paper file of such prescriptions organized chronologically by fill date. In the event that DEA requests an electronic list of such prescriptions in sequential order by prescription number, Walgreens' Department of Pharmaceutical Integrity will provide such a list upon request within a reasonable time. Paper prescriptions will be maintained at the registered location of the pharmacy that dispensed them for a period of the longer of two (2) years or that required by applicable state law.

3. Walgreens' retail pharmacies utilize a computer application for the storage and retrieval of refill information for original paper prescriptions. For prescription refills, Walgreens will follow the procedures outlined in 21 C.F.R. § 1306.22(f). To the extent that DEA wishes to retrieve electronic records regarding refills, Walgreens' Department of Pharmaceutical Integrity will facilitate responses to such requests, including by providing such information to DEA upon request in a manner that is sortable and retrievable by prescriber name, prescriber DEA registration number, patient name, patient address, drug dispensed, date filled, and last name of dispensing pharmacist.
4. Walgreens remains committed to properly training its pharmacy personnel to deal with evolving diversion-related issues. Walgreens will continue to enhance its Good Faith Dispensing Policy and training materials to identify "red flags" of potential diversion for pharmacists to consider in making professional judgments regarding dispensing of controlled substances. Walgreens will train its pharmacy personnel at least annually on Good Faith Dispensing and will update the Good Faith Dispensing Policy and training materials to respond to changing diversion threats of which Walgreens is aware. DEA will share information with Walgreens periodically regarding circumstances that may present "red flags" of potential diversion. Walgreens' training program will also instruct pharmacists and supervisory personnel to contact the Department of Pharmaceutical Integrity, as appropriate, to address specific problematic issues arising with particular patients or physicians, so that the Department of Pharmaceutical Integrity can assess and respond to such issues. Pharmacist training will also cover instruction on how to assist DEA in obtaining records as required by this Agreement or any regulations.
5. Walgreens will maintain procedures to verify that the DEA registration number for the issuing prescriber of a controlled substance is a current, valid registration number. Such verification shall be performed using information from the National Technical Information Service (NTIS) database or similarly reliable third party database where DEA registration changes are recorded. Walgreens agrees to maintain a system integrating NTIS data with Walgreens' computer system that will: (1) update NTIS registration data on a weekly basis; and (2) prevent a pharmacy from filling a controlled substance prescription using a registration number not listed in such NTIS data until such prescriber's valid registration number is confirmed.
6. Beginning in 2014, Walgreens will exclude any accounting for controlled substance prescriptions dispensed by a particular pharmacy from bonus computations for pharmacists and pharmacy technicians at that pharmacy.
7. For each retail pharmacy, Walgreens will maintain, either electronically or in paper form, a log of pseudoephedrine purchases that can be made available upon request to authorized DEA personnel. To the extent that printing or copying of such a log from electronic records at a pharmacy would be unduly laborious or time-consuming, DEA agrees that Walgreens' Department of Pharmaceutical



Integrity will facilitate transmission of such information, including through transmission of electronic records to DEA.

C. Distribution Centers

1. Within one (1) week of the effective date of this Agreement, Walgreens will designate a DEA contact point in its Department of Pharmaceutical Integrity to address inquiries regarding suspicious order monitoring and reporting. At least one (1) existing employee at each Walgreens distribution center that distributes controlled substances will receive appropriate training on suspicious order monitoring requirements and on reporting relevant issues to the Department of Pharmaceutical Integrity.
2. For purposes of complying with suspicious order monitoring and reporting requirements for orders to be supplied by a Walgreens distribution center, Walgreens will maintain the tolerance threshold, ceiling limits, and other elements of its current suspicious order monitoring and reporting system, either for the duration of this Agreement or until Walgreens distribution activities are transitioned to a third party. Walgreens will endeavor to conduct its evaluations of "orders of interest" identified by its tolerance thresholds and ceiling limits within four (4) business days in most cases, and shall inform DEA Field Offices of orders that Walgreens has determined are "suspicious" within two (2) business days of making any such determination. Walgreens agrees not to ship any "order of interest" or "suspicious order" in whole or in part unless and until Walgreens resolves the reason(s) that caused it to designate the order as an "order of interest" or a "suspicious order." Within ninety (90) days of the effective date of this Agreement, suspicious order reports shall identify reason(s) an order was determined to be suspicious, and the registration number for the specific Walgreens distribution center that would have received the order at issue.
3. Within eighteen (18) months of the effective date of this Agreement, Walgreens will initiate enrollment in and operationally implement DEA's Controlled Substance Ordering System (CSOS) for orders of all Schedule II controlled substances placed by its retail pharmacies to its distribution centers.